

HYPODERMIC INJECTION SYSTEMBACKGROUND OF THE INVENTIONCross Reference to Related Application

This application claims priority of U.S. Provisional Application No.60/126,062,  
5 filed March 25, 1999, under Title 35, United States Code, Section 119(e).

Field of the Invention

This invention relates to hypodermic injection systems, and more particularly to  
injection systems wherein the injectate is held in containers, and the system discharges  
the injectate from the containers. The invention finds particular use as a multi-channel  
10 injection system.

Description of the Prior Art

Hypodermic injection systems are widely used throughout the world today, both  
with respect to humans and with respect to animals. Moreover, there are many situations  
when multiple injections made simultaneously are either required or would be helpful.

15 Sometimes, different materials can be injected (often referred to herein as "injectates")  
for protecting against a variety of diseases, for serving as components for a single  
disease, for providing added health benefits to humans or animals, such as by way of  
added vitamins, minerals, etc., or to provide improved characteristics, such as to cause  
cattle to provide more milk, to enhance their growth, or to deliver  
20 immunopharmaceutical compounds to inhibit the reproductive system in food producing  
animals, or a particular type of medical procedure in humans. In mass injection  
programs, such as injecting vast numbers of people in third world countries or large  
numbers of animals, a considerable amount of time could be saved if multiple injections  
could be made simultaneously rather than sequentially. Although there are many  
25 advantages in simultaneous multiple injections, for example, in the case of young  
children whose vaccination schedules call for four or more injections during a single  
office visit, it would be a great advantage to deliver all of the vaccines in a single event  
to sharply limit the mental trauma that often occurs. In addition, there is the constant  
danger of needle sticks to the doctor, nurse or other person giving the injection, and the  
30 threat of disease, such as HIV and AIDS, which should be avoided.

For injection systems which are used to give many injections, such as to large

groups of people or large numbers of animals, the system is necessarily slowed down if individual proper doses of injectate must be loaded into the injection system or if preloaded injectate containers must be manually or otherwise slowly loaded and then placed into the injection system. There is a major need for injection systems, particularly

- 5 multiple injection systems, which can quickly and efficiently have proper doses of the injectate loaded into the system, the injection process made, and the system reloaded quickly to continue the injection process. There is likewise a great need for the foregoing type of systems which avoids needle sticks to the person making the injection and to avoid contact with either the injectate or the injecting portion of the system by any
- 10 individual during or following the injection process.

#### SUMMARY OF THE INVENTION

An object of the present invention is to provide a hypodermic injection system for providing injectate from containers holding the injectate in an efficient and safe manner.

- 15 An object of the present invention is to provide a hypodermic injection system for avoiding needle sticks in the person administering the injection.

Another object of the present is to provide an injection system for simultaneously providing at least two injections, and further including means for preventing needle sticks to persons who are not supposed to be injected.

- 20 It is yet another object of the present invention to provide an injection system wherein the injectate is held in cartridges having injection orifices through which the injectate passes and enters the desired body.

It is an additional object of the present invention to provide an injection system for administering injectate from at least two cartridges.

- 25 Yet another object is to provide an injection system for providing injectate from at least two cartridges under jet pressure through injection orifices in each of the cartridges.

Another object of the present invention is to provide an injection system having at least two cartridges with perforators through which the injectate flows.

- 30 Another object of the present invention is to provide an injection system having energy storage means for energizing the system to make the injection, and a motor

PCT/US00/07470

operable system for re-energizing the system in a fast and economical manner.

It is yet another object of the present invention to provide a cartridge injection system having biasing means for forcing injectate from at least one cartridge into a body, where the biasing means is placed in a cocked condition by an electric motor.

5 It is a related object of the present invention to provide a motor-operated injection system wherein the electric motor is held in a handle for the injection system.

Yet still another object of the present invention is to provide an injection system having biasing means for urging injectate from a cartridge into a body, and a loading station for energizing the biasing means in a fast and economical manner.

10 Another object of the present invention is to provide a hypodermic injection system having a container holding member for holding injectate containers, the holding member with the container members being disposable after an injection without requiring any physical contact or handling of the disposable portion by the user.

Another object of the present invention is to provide a hypodermic injection  
15 system for simultaneously injecting injectate from at least two cartridges, the cartridges being disposable after an injection without any physical contact or handling of the disposable portion by the user.

Another object of the present invention is to provide an injection system for injecting fluid from at least one cartridge, the system having guard walls for preventing  
20 splashing of the injectate during the injection process.

A further object of the present invention is to provide a hypodermic injection system for injecting injectate from at least one cartridge, the cartridge(s) being held in position by a disposable front plate.

Another object of the present invention is to provide a multi-cartridge injection  
25 system with one or more springs for applying pressure to the cartridges to dispense the injectate, and a latching apparatus for cocking and releasing the spring(s).

Yet a further object of the present invention is to provide a multi-channel injection system wherein the injection means are provided in close proximity to enable multiple multi-channel injections safely and effectively.

30 Another object of the present invention is to provide an injection cartridge, the cartridge having a dispensing end with an orifice or perforator through which the

injectate can be dispensed, and a movable plunger in the cartridge which can be moved into the injectate-holding portion of the cartridge to effect the dispensing of the injectate.

An additional object of the invention is to provide an injection cartridge for holding at least two components of an injection dosage.

5 A further object of the present invention is to provide an injection system for a plurality of cartridges, the cartridges having plungers for dispensing the injection injectate in the cartridges, the injection system further having a carriage with rams for moving towards the plungers to drive the injectate from the cartridges, and means for resetting the carriage in a cocked position.

10 It is yet another object of the present invention to provide a hypodermic injection system for dispensing injectate from at least one cartridge, the system having biasing means which is placed and held in the cocked position in accordance with a sensing signal indicating whether or not a cartridge is loaded in the system.

15 It is a general object of the present invention to provide an improved hypodermic injection system which can be used for one or more injections at the same time, which is economical and fast to use with a large number of people or animals, which prevents inadvertent needle sticks, and which prevents user contact with potentially contaminated surfaces following an injection procedure..

Other objects and advantages will become apparent to those skilled in the art  
20 from the description to follow and from the appended claims.

The foregoing objects are achieved according to the preferred embodiment of the invention. In one preferred embodiment, a jet hypodermic injection system is provided for holding at least one cartridge for holding a serum, a vaccine or other injectate. The cartridge preferably has a dispensing end with an end portion having a channel with an  
25 exit nozzle being an orifice. A plunger is provided in the cartridge, and an injectate is disposed between the plunger and the end portion. The end portion could alternatively have a perforator rather than an orifice for the exit nozzle. The system includes a housing having a disposable front end plate with holes having holding surfaces for holding the forward end of the cartridges. The housing houses a movable carriage with  
30 rams for moving the plungers through the respective cartridges. The carriage is movable between a set position and a dispensing position. One or more springs move or drive the

carriage from its set position, wherein the springs are in a cocked position, to a dispensing position wherein the carriage carries the rams for moving the respective plungers through the cartridges to force injectate through the respective channels and exit nozzles into the body being injected. The spring(s) are held in a cocked position by a  
5 releasable latch, which could be a solenoid piston which is actuated when a cartridge sensor emits a signal to the solenoid according to whether a cartridge or cartridges are loaded in the housing.

The carriage, in a preferred embodiment, is moved from its dispensing position to its set position, and for setting the spring(s) to their cocked condition, by a motor  
10 driven cam. A cam follower extends from the carriage, and the motor rotates the cam which moves the cam follower, and hence the carriage, to the set or cocked position.

The spring(s) are preferably guided and positioned by movable rods which extend between the carriage and the rear part of the housing through which they extend.

A fixed member on the rod(s) defines a shoulder for supporting one end of the spring(s);  
15 the other end of the spring(s) engages the inner part of the rear wall of the housing. As the carriage moves towards the set position, it moves the respective rods and compresses the spring(s) to their cocked position.

The front plate for holding the respective cartridges is ejectable or catapulted away from the injector after the cartridges have been used, and the plate with the spent  
20 cartridges are thereby disposed. This avoids the problems of needle sticks or any contact with contaminated surfaces by the doctor, nurses or other health care workers administering the injection, and also precludes unsafe and illegal use of spent cartridges.

In a preferred embodiment, the cam or other carriage resetting apparatus is moved from the final position to an initial position by means of a motor having a motor-  
25 driven tool designed for rotating the cam or other apparatus. A loading station can be provided for resetting the cams of one or more injection systems according to the invention, which is preferably done when new cartridge(s) are to be loaded in the system. Alternatively, the housing can be held with a handle designed to carry the motor and possibly a power source for the motor. The system is ideally suited for injecting large  
30 masses of people or animals in a safe and fast manner, providing individual or multiple injections.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a pictorial view of a hypodermic injection system of the invention showing a front end with all six injectate cartridges having orifices for the exit nozzles;

5 Figure 2 is a pictorial view of the system illustrated in Figure 1, showing the release and disposal of a used front end portion of the system;

Figure 3 is a pictorial view of the disposable front end of the preferred embodiment of the invention;

Figure 4 is a pictorial view of the front end of the invention showing the center two cartridges having orifices loaded in the front end and the four outer cartridge 10 locations having dummy loads;

Figure 5 is a pictorial view of an embodiment of the invention showing the two center cartridges having perforators, and the four outer cartridge locations having dummy loads;

Figure 6 is a transparent pictorial view of a cartridge according to the invention;

15 Figure 7 is a cross-sectional view of the preferred embodiment of the energy storage part of the system shown in Figure 1;

Figure 8 is a pictorial view of another preferred embodiment of the invention showing a loading station for cocking the energy storage part of the system;

Figure 9 is a pictorial view of the rear portion of the embodiment shown in 20 Figure 8; and

Figures 10-12 are schematic views of dispensing portions for a six-channel injection system according to the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to Figures 1 and 2, a preferred embodiment of the invention is shown.

25 These figures show a hypodermic injection system 1 having a housing 3 and a handle 5. Housing 3 includes a front end or plate 7 having an injection trigger 9 and a front end release trigger 11. Trigger 9 can be in the form of a rotatable lever, whereas trigger 11 can be a depressible button. System 1 is shown for delivering six simultaneous injections as described below, although the number can be from one to N (i.e., any 30 number of injections).

Referring specifically to Figure 2, an important advantage of the present

- invention is the ease of disposability of the front end with the expended cartridges to avoid inadvertent touching of the injection portion of the system and, if perforators or nozzles are used for the exit nozzles, the possibility of inadvertent needle sticks by the user. This easily precludes cross-contamination and disease from both blood and the
- 5 injectate on the front end of the injection system. Figure 2 shows injection system 1 following an injection. Front plate 7 is one version of a holding member for holding cartridges 13. Prior to an injection, front plate 7 holding cartridges 13 is releasably locked in housing 3 as shown in Figure 1. As explained in further detail below, the cartridges each hold a required dose of an injectate, which often is a serum or a vaccine.
- 10 The front part of cartridges 13 are held in front plate 7, and a rearwardly part of the cartridges are supported and held in a holding fixture 15.
- After an injection has been given from the cartridges loaded in system 1, the user actuates front end trigger 11 which withdraws locking members 17 which have entered grooves 19 in front plate 7, and which further releases the springs located in the mating
- 15 holes at position 21 to exert a spring force urging front end 7 with cartridges 13 forwardly away from housing 3, to catapult these parts from housing 3 for disposal, such as into a container B designed to hold contaminated goods. No person or animal touches front plate 7 or cartridges 13 following the injection process and during the disposal of front plate 7.
- 20 ~~31~~ Front plate 7 is shown in further detail in Figure 3. As explained earlier, front plate 7 is one of many possible devices for holding the injectate containers, such as cartridges 13. Front plate 7 includes an external front surface 23 and a rearwardly extending portion 25 into the opposite sides of which are provided grooves 19. Front plate 7 can be slid into place and grabbed by locking members 17 near the front of
- 25 housing 3, which are received in grooves 19, these members 17 being withdrawn upon the actuation of trigger 11. Alternatively, locking slides or the like can be removably inserted into grooves 19 to lock front plate 7 to housing 3 (of which the front end forms a part), the front plate being ejectable from the remainder of housing 3 once the locking members 17 are removed from grooves 19. Front end 7 further has holes 29 with
- 30 holding surfaces 31 for gripping the forward ends of cartridges 13 which are preferably press fit into holes 29 to hold the cartridges in place. The outer surfaces of cartridge 13

can have a high friction surface if necessary, to assure a firm grip. Guard rings 33 are provided around each of holes 29 in order to prevent the splashing of blood or of injectate as it flows through the exit nozzle of cartridge 13, particularly during the injection process. An additional splash ring 35 can also be provided, as shown in Figure 5 2, to add more protection against splashing.

Front plate 7 or other holding members are disposable as explained above. In order to maintain the sterility of the front end, it is provided in a package for keeping the front end sterile. Sterile packaged cartridges can be filled at the site of the injection procedure, or they can be delivered already filled with the selected vaccines ready for 10 insertion into front plate 7. Alternatively, the front end can be provided with cartridges previously inserted and filled with the proper dosage of the respective injectate to be contained therein, all of which would be provided in the sterile package of the front end in which they are being gripped. It should be noted that front end 7 could hold one cartridge, six as shown, or indeed any number of cartridges. For various practical 15 reasons as discussed below, it is anticipated that no more than six injections would be simultaneously given.

Figure 4 shows front plate 7 with six cartridges 13 loaded therein. It is not necessary that all cartridge locations contain dispensable injectate. Thus, as explained earlier, plate 7 has rearwardly extending portion 25 and opposed side grooves 19. Plate 7 20 could be slid behind removable locking members 17 which would extend into grooves 19 and would be removed when front plate 7 and cartridges 13 are ejected or catapulted from housing 3. Referring to the front portion of cartridge 13, an orifice 35 is the exit portion for the two active channels shown in Figure 4 and they extend through the forward portion of cartridge 13. The orifice is so designed that, in the preferred 25 embodiment of the invention, it defines the path for the jet flow of the injectate from cartridge 13. Orifice 35 could be replaced with a perforator, such as perforators on the order of 0.5 to 1.0 mm in length, as disclosed in U.S. patent application Serial No. 08/738,303, as shown as perforators 36 in Figure 5. The use of perforators would allow for lower injection pressures and a reduction, if not the total elimination, in the amount 30 of injectate fluid remaining on the surface following an injection. Experimental programs by the inventors have shown that perforators would sometime improve the

efficacy and also reduce impact trauma to the patient.

As explained earlier, six cartridge locations are shown. It was explained that any number of cartridges with respective injection channels could be provided. However, the protocol suggested by the Center for Disease Control (CDC) limits the number of 5 childhood injections to a maximum of four during a single visit to a health care facility. The CDC apparently feels that the number of suggested injections during an office visit might increase as more vaccines become available. The size of the patient, and the location of the injection site on the body, will limit the volume of fluid that can be realistically delivered to an injection site. This factor will no doubt be different for 10 children, adolescents and adults, for example, military personnel (who often require multiple vaccinations when entering the service or being deployed to different regions of the world).

As in Figure 4, the apparatus shown in Figure 5 need not have all cartridges containing dispensable injectate. Other cartridges, such as inactive or dummy load 15 cartridges, could be used lacking injectate at those channels. Such inactive cartridges could be coded, such as with different colors. In this case, Figure 5 shows perforators 36 at the active channels, and dummy cartridges 37 at the inactive channels.

Figure 6 shows an injectate container in its preferred form as cartridge 13. Cartridge 13 has an outer wall 38 and an inner wall 39 which defines a tube 41. Slidable 20 into tube 41 is a plunger 43 with a seal at its outer circumference to prevent leakage out the back end and which can be made from an elastomeric material, such as a rubber-like compound, plastic or even glass, but with a rubber seal. Plunger 43 is dimensioned to engage inner wall 39 in a fluid-tight manner. Plunger 43 can have two wall-engaging cylindrical portions 45 (towards the front) and 47 (towards the rear) to further discourage 25 leakage during an injection. Plunger 43 defines an injectate-holding portion 49 of cartridge 13, between plunger 43 and a forward part 51 of cartridge 13 having a channel 53 which terminates in orifice 35. The portion of cartridge 13 at its forward end has a smaller diameter than does the rearward part, and is preferably press fit into front plate 7 as explained earlier. The rear part of front plate 7 preferably engages a shoulder 55 when 30 cartridge 13 is press fit into plate 7.

Cartridge 13 could be filled on-site or could be filled off-site, depending on the

circumstances. Furthermore, cartridges 13 could be preloaded into the holding member such as front plate 7 at the site where the system is to be used, or it can be done off-site. When done off-site, the cartridge could be filled and sent to the loading facility separately from the front plate, or they could be preloaded into the front plate (or other 5 holding member) and provided in a sterile package.

Cartridges 13 could be designed for lyophilized vaccine by providing two compartments that are separated by an easily rupturable seal, such as seals 56 shown in dotted lines. One compartment would contain the lyophilized vaccine, medication or serum, and the adjoining compartment would contain the correct amount of fluid for 10 mixing it. Means could also be provided for rupturing the seal and mixing the ingredients together when a cartridge is inserted into front plate 7 or when the cartridge-laden plate is inserted into the injector. A means of mixing lyophilized vaccines in the cartridge at the time of injection is described in U.S. Patent No. 5,080,648.

Turning next to Figure 7, which is a cut-away view of system 1 without the handle or triggers discussed earlier, <sup>System</sup> 1 has housing 3 and end plate 7, as explained earlier. To avoid undue complexity in Figure 7, the means for ejecting or catapulting front plate 7 away from the injector are not shown. Housing 3 houses a carriage 57 which has extending from it rams or plunger rods 59. A set of three springs 61 (for each of the three cartridges shown, there being six cartridges and springs in 20 system 1) extends around the set of drive rods 63, each of which having nuts or movable spring supports 65. Supports 65 are movable along threaded rods 63 to provide a means to adjust spring preload and, therefore, injection pressure. Housing 3 has a rear wall 67, and springs 61 have their rear ends in contact with stationary wall 67. A set of holes 69 are provided in wall 67 through which rods 63 pass and are movable. A cap or shoulder 25 71 is provided at the rear end of rod 63 for both preventing rod 63 from entering the inside chamber of housing 3 and for cooperating with a latching assembly discussed below. The latching assembly includes a solenoid 73 for each spring (however, only two are shown) and each having pistons 75 which in their energized state are inserted in front of caps 71 as part of the latching assembly. A cartridge sensor switch 79 is closed when 30 a cartridge is installed in the appropriate holding portion of housing 3, thereby retracting piston 75 away from the path of moving rod 63 and cap 71. This is illustrated in the

*Portion*  
upper position of Figure 7.

A cam 81 rotatably mounted on a shaft or axle 83 is provided for resetting carriage assembly 57 as explained below. A cam follower 85 having follower arm 87 connected to carriage assembly 57 and a roller 89 which follows the contour of cam 81.

5 Figure 7 shows two cartridges 13 loaded in the two upper chambers 88 of the system, and no cartridge is included in bottom cartridge chamber 88. The two cartridges have plungers 43. Front plate 7 has guard rings 33 as discussed earlier.

Figure 7 shows injection system 1 after an injection has been made. Carriage 57 is in its dispensed position, having been moved all the way to the right to the front of 10 housing 3. Rams 60 have pushed plungers 43 to the forward end of cartridges 13 to discharge the injectate from the two active cartridges during the injection process. In order to reload housing 3, shaft 83 and cam 81 are rotated clockwise by a motor (as discussed below) causing roller 89 to roll across the periphery of cam 81 and move cam follower 85 and carriage 57 rearwardly to the left in Figure 7. The contour of cam 81 is 15 configured to effect this movement as its radius increases at the point of contact with roller 89. As carriage assembly 57 is moved to the left, rods 63 are forced to the left as well. Nuts 65 compress springs 61 until cam 81 has completed its rotation from an initial position to a final position, at which time springs 61 are totally compressed and rods 63 are at their leftmost or rearmost position. At this time, rams or drive rods 60 are 20 withdrawn from member 15 providing a convenient time to eject the used front end away from the injector leaving room for new cartridges having proper dosages of injectate in them, inserted into member 15. When cartridges 13 are properly installed, they again actuate switch 79, which emits a sensing signal to effect the movement of solenoid piston 75 away from the path of caps 71 on rods 63. Since no cartridge is inserted in the 25 lower channel of Figure 7, its piston 75 is extended in front of shoulder or cap 71, thus preventing that spring from contributing to the injection process.

In order to commence an injection with carriage assembly 57 in its set or cocked position and springs 61 in their cocked position as well, the user of system 1 actuates trigger 9. This action will either release a mechanical latch (not shown) or will provide a 30 slight rotation to cam 81 to allow roller 89 to release as it moves onto the sharp drop off *go* *87* of cam 81.

Springs 61 drive rods 63 forwardly to move carriage assembly 57 forwardly, and thereby drive rams 60 against plungers 43 to force injectate through channels 51 of cartridges 13 and out through orifices 35 (or perforators 36). After the injection, the user actuates trigger 11, causing the catapulting of front plate 7 and cartridges 13 from the 5 unit for disposal, such as into a barrel B.

In a related embodiment, the details of which are not shown, when injection cartridges 13 are slid into the injection chamber, they could actuate a connecting rod to mechanically actuate the spring-loaded latch 75 to retract it to the non-latched position.

There may be situations in which housing 3 is not totally loaded with cartridges 10 13. In these cases, as shown in the bottom portion of Figure 7, there is no cartridge 13 in the lower chamber and the lower rod 63 has not been released from its cocked or set position. For the case where no cartridge is present when carriage 57 is first moved to the left, shoulder 71 is mechanically able to move past extended piston 75, but is not able to move past extended piston 75 when trying to move to the right unless a cartridge is 15 first inserted into the channel.

In the embodiment of the invention shown in Figures 1 and 2, a motor and power source are included in handle 5 for resetting cam 81 to its initial position. A unit such as that in Figures 1 and 2 is portable, easy to use, and particularly easy to use for injections for large numbers of people or large numbers of animals. Even though injector system 1 20 is small, lightweight and easy to handle, in some situations it might be advantageous to make the hypodermic injection system according to the invention even smaller and lighter, when masses of people or animals are being injected, such as where a health care worker administers hundreds or thousands of injections over the course of a day. Accordingly, the preferred embodiment shown in Figures 8 and 9 form another aspect of 25 the present invention.

Figure 8 shows two hypodermic injection systems 1 according to the invention, in this case without a handle. However, a loading station 101 is provided for putting the carriage in its set or cocked position, and for compressing or cocking the springs. Thus, housing 3 houses cam 81, springs 61, and injection chambers 88 for cartridges 13, as 30 explained earlier. Loading station 101 has a series of walls defining compartments 103, 105 and 107 for each receiving an injection system 1. Each compartment 103, 105, 107

includes a drive mechanism 109 having a hexagonal shape for engaging a corresponding portion of cam axle 83. An enable button 111 is preferably provided so that when a system 1 is inserted in a compartment 103, 105, 107, button 111 is depressed and drive mechanism 109 rotates cam 81 to its loaded or injection ready position. The drive mechanism stops rotating upon the actuation of an internal disable switch which detects the correct amount of rotation. These injector positions could be sensed electronically rather than using the button switches as shown. The hand-held portion, system 1 of Figure 8, is then removed from station 101 for an injection to be made. The system is then reloaded and reset with loading station 101. While injection system 1 in Figure 8 10 has the same form (less the handle) as shown in Figure 1, in an actual commercial system, it will have a shape that is easily held by the user when giving an injection.

The rear portion of the apparatus shown in Figure 8 is shown in Figure 9. Loading station 101 can be energized using the AC input 113 or a DC input 115. An on/off switch 117 is also provided. The power can be an AC grid or battery, or can use 15 compressed gas, ignitable gas such as butane, hydraulic drive, or manual operation using a hand crank or a foot pedal. Systems 1 shown in Figures 8 and 9 can be easily moved when the injection procedures are completed. Load stations 101 need not be picked up by the health care worker when an injection is given. Loading station 101 and system 1 are only brought together when spring compression is needed, and this could even be 20 done using a long speedometer-type cable connection instead of a direct contact interface as shown in Figures 8 and 9. Even though Figures 8 and 9 show DC and AC power inputs, manual loading is also possible in case of power failure or lack of power at a particular location.

Although Figure 7 shows a spring for each cartridge, a single spring is also 25 possible. Other means for providing pressure for dispensing injectate from the holding members are possible. Other springs besides wire springs could be used as well, including resilient plastic springs, elastomeric springs such as rubber or rubber-like materials, and possibly electro-magnetic fields. Although the cam system shown in Figure 7 has been found to be effective, other means for setting the system would also 30 apply. For example, there could be gearing systems, linear systems, such as those with linear gears, pawl and gear mechanisms, belts, rollers, and the like could be employed.

The injectate containers have been shown as being rigid, but in some situations flexible plastic holders might be appropriate as well.

- Reference is now made to Figures 10, 11 and 12, which relate to a configuration analysis of the exit nozzles. The configuration of exit nozzles is particularly important
- 5 with regard to multiple simultaneous injections which are given to a limb of a small child, wherein the available surface area needed to deliver an effective injection is limited. In addition, if multiple simultaneous injections are given, it is preferable to prevent or at least minimize the overlap of injectates in the child's tissue in order to limit the possibility of an adverse reaction if the injectates should mix in the target tissue. In
- 10 order to achieve this non-overlap condition, the injections must be delivered a certain minimum distance apart. For this reason, the inventors have carried out a geometric analysis to determine the configuration of the exit nozzles that uses the least amount of surface area while still preventing overlap of the vaccines in the tissue. In order to make this analysis, an analysis of the volume of tissue affected by an injection was required.
- 15 Accordingly, a six-channel system with a delivery volume of 0.2 cc for each channel was assumed. However, it was also noted that the standard single-shot dose is actually 0.5 cc. It is possible that smaller doses from vaccine manufacturers may occur with multiple channel injections. The configurations considered by the inventors were rectangular, pentagonal with one orifice in the center, and hexagonal.
- 20 Pathological observation by the inventors made during the course of a U.S. Department of Agriculture study showed that the injectate spreads very little in the tissue when delivered by needle and syringe; i.e., there is a pooling effect. The research showed that a 0.2 cc needle and syringe injection occupied a spheric volume in the tissue of 0.278 cc (done empirically). When an injection is given by a jet injector, the spheric
- 25 volume of tissue affected is 8.79 times that of a needle and syringe (empirical). Thus, the spheric volume occupied by 0.2 cc of injectate delivered by jet injection would be 8.79 times 0.278 cc or 2.44 cc.

- The diameter of a sphere D is given by dividing the volume by 0.5236 and then taking the cube root of the result. Thus, a jet injection of 0.2 cc that occupies a sphere of
- 30 2.44 cc would have a diameter of 1.67 cm. Using this diameter as the minimum allowable distance between each of the six exit nozzles, an analysis of the three

configurations shows that the rectangular option occupies the smallest surface area at the injection site. Based on these calculations, a six channel rectangular housing has been designed and fabricated as shown in Figures 1, 2, 3 and 4. The result of these calculations is shown in Figures 10-12, wherein Figure 9 shows a rectangular configuration, Figure 10 shows a pentagonal configuration, and Figure 11 shows a hexagonal configuration. Arrows 121 in Figure 10, 123 in Figure 11, and 125 in Figure 12 are each 1.67 cm. An arrow 127 in Figure 11 is 1.96 cm. The results of the foregoing research is shown in the following table:

Orifice Configuration and Surface Area Needed to Prevent Overlap of Six 0.2 cc Shots

| <u>Orifice Configuration</u> | <u>Surface Area (cm<sup>2</sup>)</u> |
|------------------------------|--------------------------------------|
| Rectangle                    | 5.58                                 |
| Pentagon                     | 6.63                                 |
| Hexagon                      | 7.24                                 |

- 10 The invention has been described in detail with particular emphasis on the preferred embodiments thereof, but variations and modifications within the spirit and scope of the invention may occur to those skilled in the art to which the invention pertains.